4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0168]

Agency Information Collection Activities; Proposed Collection; Comment Request; Disclosure Regarding Additional Risks in Direct-to-Consumer Prescription Drug Television Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on research entitled "Disclosure Regarding Additional Risks in Direct-to-Consumer (DTC) Prescription Drug Television (TV) Advertisements (Ads)." This study will investigate the impact of limiting the risks presented in DTC prescription drug television ads to those that are serious and actionable, and including a disclosure to alert consumers that there are other product risks not disclosed in the ad.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the

Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the

collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Disclosure Regarding Additional Risks in Direct-to-Consumer Prescription Drug Television Advertisements--(OMB Control Number 0910-NEW)

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes the FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA-regulated products in carrying out the provisions of the FD&C Act.

Prescription drug advertising regulations (21 CFR 202.1) require that broadcast (TV or radio) advertisements present the product's major risks in either audio or audio and visual parts of the advertisement; this is often called the "major statement." There is concern that as currently implemented in DTC ads, the major statement is often too long, which may result in reduced consumer comprehension, minimization of important risk information and, potentially, therapeutic noncompliance due to fear of side effects. At the same time, there is concern that DTC TV ads do not include adequate risk information or leave out important information. These are conflicting viewpoints. A possible resolution is to limit the risks in the major statement to those that are serious and actionable, and include a disclosure to alert consumers that there are other product risks not included in the ad. For example, the disclosure could be, "This is not a full list of risks and side effects. Talk to your doctor and read the patient labeling for [drug name] before starting it." The Office of Prescription Drug Promotion (or we) plans to investigate the effectiveness of this "limited risks plus disclosure" strategy through empirical research.

Our hypothesis is that, relative to inclusion of the full major statement, providing limited risk information along with the disclosure about additional risks will promote improved consumer perception and understanding of serious and actionable drug risks. We will also investigate other questions such as whether overall drug risk and benefit perceptions are affected by these changes. To examine differences between experimental conditions, we will conduct inferential statistical tests such as analysis of variance. With the sample size described below, we will have sufficient power to detect small- to medium-sized effects in the main study.

Participants will be consumers who self-identify as having been diagnosed with one of three possible medical conditions. All participants will be 18 years of age or older. We will exclude individuals who work in healthcare or marketing settings because their knowledge and experiences may not reflect those of the average consumer. Recruitment and administration of the study will take place over the Internet. Participation is estimated to take approximately 30 minutes.

Within medical condition, participants will be randomly assigned to view one of four possible versions of an ad, as depicted in table 1 below. One version will present the full major statement without the disclosure regarding additional risks (conditions C, G, and K). This version will implement existing ads in the marketplace. Stimuli variations for the other three versions will be achieved by replacing the audio track of the original ad with the revised risk and disclosure statements described above. Thus, a second version of the ad will include the full major statement plus the disclosure about additional risks (conditions A, E, and I). A third version will include an abbreviated statement of risks without the disclosure about additional risks (conditions G, H, and L). The fourth version will include an abbreviated statement of risks as well as the disclosure about additional risks (conditions B, F, and J).

After viewing the ad, participants will respond to questions about information in the ad. Preliminary measures are designed to assess perception and understanding of product risks and benefits; perception and understanding of the disclosure about additional risks; perceptions of product quality; intention to seek more information about the product; and perceptions of trust/skepticism regarding product claims and the sponsor. The questionnaire is available upon request.

Table 1:--Study Design

		Major Statement	
Medical Condition	Disclosure Regarding Additional Risks	Version 1	Version 2
1	Present	A	B
	Absent	C	D
2	Present	E	F
	Absent	G	H
3	Present	I	J
	Absent	K	L

Note: Version 1 = current major statement; Version 2 = abbreviated major statement.

FDA estimates the burden of this collection of information as follows:

Table 2.--Estimated Annual Reporting Burden[1]

Disclosure Regarding Additional Risks in DTC Prescription Drug TV Ads	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Pilot study screener	3300	1	3300	0.03 (2 minutes)	99
Main study screener	10000	1	10,000	0.03 (2 minutes)	300
Pilot study	500	1	500	1	500
Main study	1500	1	1500	0.50 (30 minutes)	750
Total					1649

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: February 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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